

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 8:18-cv-883-PWG

INDICATIVE RULING

Upon consideration of Defendants' request for an indicative ruling on a motion under Federal Rule of Civil Procedure 60(b) for a 120-day extension of the premarket application deadline imposed by the Court's remedy order [ECF No. 127] in light of the global outbreak of respiratory illness caused by a new coronavirus, the Court hereby **STATES** that

The Court would **GRANT** the motion if the case were remanded for that purpose; and

The Court would **MODIFY** paragraph 1 on page 12 of the remedy order to read as follows:

"1. the FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed by September 9, 2020;" and

The Court would **MODIFY** all other references in the remedy order to the "ten-month deadline for submissions" to the "September 9, 2020 deadline for submissions."

Dated: April 3, 2020

/S/
PAUL W. GRIMM
United States District Judge